



SW
AR
✓

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT: Christian Knöpfle et al. EXAMINER: Philogene, Pedro
SERIAL NO.: 09/921,233 GROUP ART UNIT: 3732
FILED: August 1, 2001 ATTY DOCK. NO.: 60,500-072
FOR: SELF-RETAINING IMPLANT AND A DEVICE FOR
SECURING THE IMPLANT

APPEAL BRIEF

Mail Stop Appeal Brief - Patent
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir or Madam:

Applicant submits the following Appeal Brief within two months of a Notice of Appeal filed on March 22, 2004, and in response to the Final Rejection set forth in the Final Office Action, dated January 4, 2005, Paper No./Mail Date 12292004. A check in the amount of \$500.00 is attached to cover the required fee for submitting this Appeal Brief. The Commissioner is authorized to charge any additional fees or credit any overpayment to Deposit Account No. 08-2789.

(1) Real Party in Interest

The real party in interest is Stryker Leibinger GmbH & Co. KG, assignee of the patent application in issue, as evidenced by an assignment recorded at Reel/Frame 012045/0035.

(2) Related Appeals and Interferences

NONE

(3) Status of Claims

Claims 1, 5-6, 10-11, 29-31, 38-41, and 44 are pending in the application. Claims 1 and 44 are independent. Claims 2-4, 7-9, 12-28, 32-37, and 42-43 have been canceled.

Claims 1, 5-6, 10-11, 29-31, 38-41, and 44 stand rejected. Claims 1, 5-6, 10-11, 29-31, 38-41, and 44 are on appeal.

(4) Status of Amendments

All amendments have been entered and are reflected in the claims in the Claims Appendix.

(5) Summary of Claimed Subject Matter

Claims 1, 5-6, 10-11, 29-31, 38-41, and 44 are on appeal. Of those, claims 1 and 44 are independent.

Referring to Figures 1 and 9, a self-retaining implant for attaching a bone cover 130 or a bone fragment 130 to a skull is generally shown at 10. The implant 10 comprises a support element 12 having an upper side 18 and a lower side 20. The lower side 20 of the support element 12 is concave in shape along sections thereof.

An extension 14 extends substantially at a right angle from the lower side 20 of the support element 12 to an end remote from the support element 12 and substantially straight between the support element 12 and the end. The extension 14 is inelastic such that the extension 14 extends rigidly from the lower side 20 of the support element 12.

Referring specifically to Figure 9, the support element 12 comprises two support arms 22, 24 extending in opposite directions from the extension 14. The first support arm 22 defines a screw hole 26 for receiving a fastener 150 to secure the first support arm 22 to the skull 140. The support element 12 has a thickness increasing in the direction of the screw hole 26. An inside 32 of the screw hole 26 is spherically curved. The second support arm 24 cooperates with the bone cover 130 or bone fragment 130 during use. The upper side 18 of the support element 12 is continuous across the second support arm 24 such that the second support arm 24 is free of any screw hole.

At least one spike 16 is disposed at the end of the extension 14 remote from the support element 12 and extends substantially parallel to the support element 12. The spike 16 has a substantially triangular form. The spike 16 extends from the extension 14 in a same direction as the second support arm 24 and cooperates with the second support arm 24 and the bone cover 130 or bone fragment 130 to anchor the implant. The second

support arm 24 has a length and the spike 16 extends from the extension 14 more than one half the length of the second support arm 24 to anchor the implant 10.

In operation, the spike 16 is first driven laterally into the bone cover 130 or bone fragment 130. At the same time, the second support arm 24 cooperates with the bone cover 130 or bone fragment 130 by sliding along a top of the bone cover 130 or bone fragment 130. Once the spike 16 is securely positioned in the bone cover 130 or bone fragment 130 (usually multiple implants 10 are driven into the bone cover 130 or bone fragment 130), the bone cover 130 or bone fragment 130 is positioned adjacent to the skull 140, e.g., in an opening defined in the skull 140. After the bone cover 130 or bone fragment 130 is in position, the first support arm 22 is secured to the skull 140 using the fastener 150.

(6) Grounds of Rejection to be Reviewed on Appeal

A. Claims 1, 6, 29-31, and 38-41

Claims 1, 6, 29-31, and 38-41 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Manthrop et al. (U.S. Patent No. 5,916,217).

B. Claim 5

Claim 5 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Manthrop et al. in view of Hair (U.S. Patent No. 6,197,037).

C. Claims 10 and 11

Claims 10 and 11 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Manthrop et al. in view of Hair and in further view of Pohndorf et al. (U.S. Patent No. 5,904,683).

D. Claim 44

Claim 44 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Manthrop et al.

(7) Argument

A. Claims 1, 6, 29-31, and 38-41

The rejection to claims 1, 6, 29-31, and 38-41 relies on the combination of Manthrop et al. with the knowledge generally available to one having ordinary skill in the art. This combination does not comport with the mandates of the MPEP for establishing a *prima facie* case of obviousness and is based on hindsight in view of the Applicant's disclosure. MPEP §§2142 and 2143.03 set forth the requirements for establishing the *prima facie* case of obviousness:

2142 Legal Concept of *Prima Facie* Obviousness

...The examiner bears the initial burden of factually supporting any *prima facie* conclusion of obviousness...

ESTABLISHING A *PRIMA FACIE* CASE OF OBVIOUSNESS

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not be based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). See MPEP §2143-§2143.03 for decisions pertinent to each of these criteria. The initial burden is on the examiner to provide some suggestion of the desirability of doing what the inventor has done. "To support the conclusion that the claimed invention is directed to obvious subject matter, either the references must expressly or impliedly suggest the claimed invention or the examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references." *Ex parte Clapp*, 227 USPQ 972, 973 (Bd. Pat. App. & Inter. 1985).

2143.03 All Claim Limitations Must Be Taught or Suggested

To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). "All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496

(CCPA 1970). If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988).

Claim 1 recites a self-retaining implant 10 for attaching a bone cover 130 or a bone fragment 130 to a skull 140. The implant 10 comprises a support element 12 having an upper side 18 and a lower side 20. An extension 14 extends substantially at a right angle from the lower side 20 of the support element 12 to an end remote from the support element 12 and substantially straight between the support element 12 and the end. At least one spike 16 extends substantially parallel to the support element 12 such that the spike 16 can be driven laterally into the bone cover 130 or bone fragment 130 prior to positioning the bone cover 130 or bone fragment 130 adjacent to the skull 140. The support element 12 further comprises two support arms 22, 24 extending in opposite directions from the extension with the first 22 of the two support arms defining a screw hole 26 therein for receiving a fastener 150 to secure the first support arm 22 to the skull 140 after the spike 16 has been driven laterally into the bone cover 130 or bone fragment 130 and after positioning the bone cover 130 or bone fragment 130 adjacent to the skull 140. The second 24 of the two support arms cooperates with the bone cover 130 or bone fragment 130 when driving the spike 16 into the bone cover 130 or bone fragment 130.

Manthrop et al. discloses an implant 110 for attaching a bone flap 16 to a skull 22. Referring to Figure 3, the implant 110 of Manthrop et al. comprises a support element having a flap clipping portion 112 and a skull clipping portion 118. An extension 124 extends downwardly from a lower side of the support element to a remote end. A pair of burrs 132 extends at an acute angle from the extension 124. In practice, multiple implants 110 are used to attach the bone flap 16 to the skull 22. In this process, each of the implants 110 of Manthrop et al. are first attached to the bone flap 16. To accomplish this, a screw 140 is secured to the bone flap 16 through a screw hole defined in the flap clipping portion 112. When secured, the burrs 132 protrude outwardly from the bone flap 16. Then, with the implants 110 secured to the bone flap 16, the bone flap 16 is positioned in an opening in the skull 22 and the burrs 132 engage the skull 22 in a "snap-fit" manner to hold the bone flap 16 in position. The implant 110 does not include a spike extending substantially parallel to the support element for driving laterally into the bone flap 16 in

combination with a screw hole in the skull clipping portion 118 for receiving a fastener to secure the skull clipping portion 118 to the skull as required by claim 1.

To serve their intended function, the burrs 132 cannot extend substantially parallel to the support element, as required by claim 1. If they did, they would not provide the gripping force required for the “snap-fit” engagement between the bone flap 16 and the skull 22. The Examiner states that it would have been obvious to form the burrs 132 at an angle of 90 degrees from the extension 124, e.g., substantially parallel to the support element, since “it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art.” (page 3 of final office action). However, Applicant respectfully submits, for the reasons presented above, that forming the burrs 132 at an angle of 90 degrees from the extension 124 would defeat the “snap-fit” engagement of the burrs 132 in Manthrop et al. With the burrs 132 at an angle of 90 degrees to the extension 124, when the bone flap 16 is positioned in the opening in the skull 22, the burrs 132 would scrape against the edges of the skull 22, as opposed to smoothly gliding into position, as provided by their disclosed angular orientation.

In summary, Manthrop et al. fails to disclose a spike extending substantially parallel to a support element for driving laterally into a bone cover or bone fragment in combination with a screw hole in a first support arm of the support element for receiving a fastener to secure the first support arm to the skull. Instead, Manthrop et al. discloses a pair of angled burrs 132 for “snap-fit” engagement with the skull 22 in combination with a flap clipping portion 112 with a screw hole 138 for receiving a fastener 140 to secure the flap clipping portion 112 to a bone flap 16. Thus, Manthrop et al. fails to disclose, teach, or suggest, all of the features required by claim 1. Therefore, Applicant submits that the Examiner has failed to establish a *prima facie* case of obviousness.

Applicant respectfully submits that dependent claims 6, 29-31, and 38-41 are also allowable based on their own merits, and their dependency to allowable claim 1.

B. Claim 5

The rejection to claim 5 relies on the combination of Manthrop et al. with Hair. This combination does not comport with the mandates of the MPEP for establishing a *prima facie* case of obviousness and is based on hindsight in view of the Applicant's disclosure.

Claim 5 is dependent on claim 1 and adds that the lower side 20 of the support element 12 is concave or spherically curved at least in sections.

Hair discloses a fastener 40 for joining a bone flap 20 to a skull 10. The fastener 40 includes a support element 50 having two support arms 50L, 50R for fitting over an upper bone layer of the bone flap 20 and the skull 10, an extension 70 extending straight from the support element 50 to a remote end, and a second support element 60 at the remote end having two support arms 60L, 60R for fitting below a bottom bone layer of the bone flap 20 and the skull 10. The support arms 50L, 50R of the first support element 50 are curved to facilitate a fit to the bone flap 20 and the skull 10. The Examiner has applied the teachings of this curvature in Hair to Manthrop et al. to arrive at claim 5.

Applicant respectfully submits that there is no teaching, suggestion, or motivation for these references to be properly combined to establish a *prima facie* case of obviousness. In the "BACKGROUND OF THE INVENTION", Manthrop et al. stresses the disadvantages of implants that protrude below the bottom bone layer of the skull or bone flap and compress the underlying brain tissue. In other words, one of the important features of the Manthrop et al. implant is that it does not protrude below the bottom bone layer and come into contact with the brain tissue. Hair, on the other hand, specifically shows the second support element 60 extending below the bottom bone layer (see, e.g., Figure. 3) for positioning between the bottom bone layer and the brain tissue. Hence, these references teach away from one another and lack any motivation, teaching, or suggestions to be combined. For this reason, Applicant respectfully submits that dependent claim 5 is in condition for allowance.

C. Claims 10 and 11

The rejection to claims 10 and 11 relies on the combination of Manthrop et al. with Hair and Pohndorf et al. For the reasons discussed in part B with respect to dependent claim 5, this combination does not comport with the mandates of the MPEP for establishing a *prima facie* case of obviousness. For this reason, Applicant respectfully submits that dependent claims 10 and 11 are in condition for allowance.

D. Claim 44

The rejection to claim 44 relies on the combination of Manthrop et al. with the knowledge generally available to one having ordinary skill in the art. This combination does not comport with the mandates of the MPEP for establishing a *prima facie* case of obviousness and is based on hindsight in view of the Applicant's disclosure.

Claim 44 recites a method of attaching a bone cover 130 or a bone fragment 130 to a skull 140 with a self-retaining implant 10. The self-retaining implant 10 comprises a support element 12 having a lower side 20, an extension 14 extending substantially at a right angle from the lower side 20 of the support element 12 to an end remote from the support element 12 and substantially straight between the support element 12 and the end, and at least one spike 16 extending substantially parallel to the support element 12. The support element 12 includes two support arms 22, 24 extending in opposite directions from the extension 14 with the first support arm 22 defining a screw hole 26 therein for receiving a fastener 150 and the second support arm 24 cooperating with the bone cover 130 or bone fragment 130. The method includes the steps of driving the spike 16 laterally into the bone cover 130 or bone fragment 130, positioning the bone cover 130 or bone fragment 130 adjacent to the skull 140 after driving the spike 16 laterally into the bone cover 130 or bone fragment 130, and securing the first support arm 22 to the skull 140 after positioning the bone cover 130 or bone fragment 130 adjacent to the skull 140.

Manthrop et al. discloses an implant 110 for attaching a bone flap 16 to a skull 22. Referring to Figure 3, the implant 110 of Manthrop et al. comprises a support element having a flap clipping portion 112 and a skull clipping portion 118. An extension 124

extends downwardly from a lower side of the support element to a remote end. A pair of burrs 132 extends at an acute angle from the extension 124. In practice, multiple implants 110 are used to attach the bone flap 16 to the skull 22. In this process, each of the implants 110 of Manthrop et al. are first attached to the bone flap 16. To accomplish this, a screw 140 is secured to the bone flap 16 through a screw hole defined in the flap clipping portion 112. When secured, the burrs 132 protrude outwardly from the bone flap 16. Then, with the implants 110 secured to the bone flap 16, the bone flap 16 is positioned in an opening in the skull 22 and the burrs 132 engage the skull 22 in a “snap-fit” manner to hold the bone flap 16 in position. Manthrop et al. relies on the burrs 132 to provide the gripping force required to secure the bone flap 16 with the skull 22. Manthrop et al. does not disclose, teach, or suggest **driving a spike laterally into the bone flap 16 and securing the skull clipping portion 118 to the skull 22 after driving the spike laterally into the bone flap 16 and after positioning the bone flap 16 adjacent to the skull 22, as required by claim 44.**

In summary, Manthrop et al. fails to disclose the steps of driving a spike laterally into a bone cover or bone fragment and securing a first support arm to the skull after driving the spike laterally into the bone cover or bone fragment and after positioning the bone cover or bone fragment adjacent to the skull, as required by claim 44. For this reason, Applicant respectfully submits that independent claim 44 is in condition for allowance.

E. Summary

The rejection to independent claims 1 and 44 based on Manthrop et al. and the knowledge generally available to a person having ordinary skilled in the art is improperly based on Applicant’s teachings. Manthrop et al. does not disclose a spike extending substantially parallel to a support element for driving laterally into a bone cover or bone fragment in combination with a screw hole in a first support arm for receiving a fastener to secure the first support arm to the skull, nor does Manthrop et al. disclose the steps of driving the spike laterally into the bone cover or bone fragment and securing the first support arm to the skull after driving the spike laterally into the bone cover or bone fragment and after positioning the bone cover or bone fragment adjacent to the skull. A

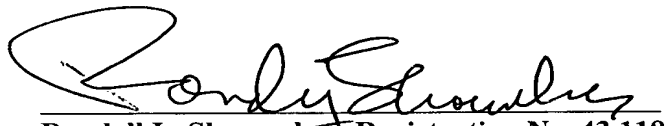
U.S.S.N.: 09/921,233

person having ordinary skill in the art, without more, would not be motivated to modify Manthrop et al. to achieve the requirements of independent claims 1 and 44. No secondary reference teaches these limitations. Thus, the Examiner has failed to establish a *prima facie* case of obviousness by failing to disclose, teach, or suggest all of the claimed limitations. Accordingly, the Board is respectfully requested to reverse the rejection of the claims as not fairly based upon the teachings of the references.

Respectfully submitted,

HOWARD & HOWARD ATTORNEYS, P.C.

May 19, 2005
Date

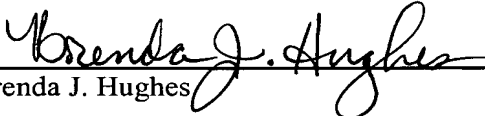


Randall L. Shoemaker, Registration No. 43,118
The Pinehurst Office Center, Suite 101
39400 Woodward Avenue
Bloomfield Hills, MI 48304-5151
(248) 723-0425

U.S.S.N.: 09/921,233

CERTIFICATE OF MAILING

I hereby certify that the attached **APPEAL BRIEF and return post card** for application serial number 09/921,233, filed August 1, 2001 are being deposited with the United States Postal Service as first class mail, postage prepaid, in an envelope addressed to the **Mail Stop Appeal Brief – Patents, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450**, on this **May 19, 2005**.


Brenda J. Hughes

G:\s\stryker\leibinger\ip00072\patent\AppealBrief.doc

(8) Claims Appendix

1. A self-retaining implant for attaching a bone cover or a bone fragment to a skull, the implant comprising:

a support element having an upper side and a lower side;

an extension extending substantially at a right angle from the lower side of the support element to an end remote from the support element and substantially straight between the support element and the end; and

at least one spike extending substantially parallel to the support element such that the spike can be driven laterally into the bone cover or bone fragment prior to positioning the bone cover or bone fragment adjacent to the skull,

wherein the support element comprises two support arms extending in opposite directions from the extension with the first of the two support arms defining a screw hole therein for receiving a fastener to secure the first support arm to the skull after the spike has been driven laterally into the bone cover or bone fragment and after positioning the bone cover or bone fragment adjacent to the skull and the second of the two support arms for cooperating with the bone cover or bone fragment when driving the spike laterally into the bone cover or bone fragment.

2-4. (Canceled)

5. The implant according to Claim 1, wherein the lower side of the support element is concave or spherically curved at least in sections.

6. The implant according to Claim 1, wherein the spike is disposed at the end of the extension remote from the support element and extends from the end of the extension remote from the support element.

7-9. (Canceled)

10. The implant according to Claim 1, wherein the support element has a thickness increasing in the direction of the screw hole.

11. The implant according to Claim 1, wherein an inside of the screw hole is spherically curved.

12-28. (Canceled)

29. The implant according to Claim 1, wherein the spike extends from the extension in a same direction as the second support arm and cooperates with the second support arm and the bone cover or bone fragment to anchor the implant.

30. The implant according to Claim 1, wherein the spike has a substantially triangular form.

31. The implant according to Claim 30, wherein the second support arm extends in a same direction as the substantially triangular spike and cooperates with the substantially triangular spike and the bone cover or bone fragment to anchor the implant.

32-37. (Canceled)

38. The implant according to Claim 1, wherein the extension is inelastic such that the extension extends rigidly from the lower side of the support element.

39. The implant according to Claim 29, wherein the second support arm has a length and the spike extends from the extension more than one half the length of the second support arm to anchor the implant.

40. The implant according to Claim 1, wherein the second support arm has a length and the spike extends from the extension more than one half the length of the second support arm to anchor the implant.

41. The implant according to Claim 40, wherein the upper side of the support element is continuous across the second support arm such that the second support arm is free of any screw hole.

42-43. (Canceled)

44. A method of attaching a bone cover or a bone fragment to a skull with a self-retaining implant comprising a support element having a lower side, an extension extending substantially at a right angle from the lower side of the support element to an end remote from the support element and substantially straight between the support element and the end, and at least one spike extending substantially parallel to the support element, wherein the support element includes two support arms extending in opposite directions from the extension with the first of the two support arms defining a screw hole therein for receiving a fastener and the second of the two support arms for cooperating with the bone cover or bone fragment, said method comprising the steps of:

driving the spike laterally into the bone cover or bone fragment;

positioning the bone cover or bone fragment adjacent to the skull after driving the spike laterally into the bone cover or bone fragment; and

securing the first support arm to the skull after positioning the bone cover or bone fragment adjacent to the skull.

U.S.S.N.: 09/921,233

(9) Evidence Appendix

NONE

U.S.S.N.: 09/921,233

(10) Related Proceedings Appendix

NONE

G:\S\Stryker\Stryker Leibinger\lp00072\Patent\Appeal Brief-5-22-05.doc